

AUG 31 2000

Section 3 - 510(k) Summary

510(k) Number: k 994022

Date Prepared: June 21, 2000

Applicant Information:

Applicant: Parallax Medical, Inc.
453 Ravendale Drive, Suite B
Mountain View, CA 94043

Contact: Bryan M. Barr
Senior Materials Scientist

Phone: (650) 934-6969
Fax: (650) 934-6965

Device Information:

Trade Name: Parallax Cranioset

Common Name: Methyl methacrylate for cranioplasty

Equivalent Devices:

The subject device is substantially equivalent to Codman Cranioplastic™, Acrylic Cranioplasty Material (K873689).

Intended Use:

Parallax Cranioset is a resinous material for repair of cranial defects.

Comparison to Predicate Devices:

This device has the same intended use and functional characteristics as the predicate device. The materials contained within Parallax Cranioset are all materials that appear in the predicate device.

Non-clinical Test Results:

Performance testing demonstrated that Parallax Cranioset is substantially equivalent to Cranioplastic with regard to functional characteristics.

Summary:

Based on the product performance information provided in this notification, the subject device has been shown to be substantially equivalent to the currently marketed predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 31 2000

Mr. Bryan Barr
Senior Materials Scientist
Parallax Medical, Inc.
453 Ravendale Drive, Suite B
Mountain View, California 94043

Re: K994022
Trade Name: Parallax Cranioset
Regulatory Class: II
Product Code: GXP
Dated: June 21, 2000
Received: June 22, 2000

Dear Mr. Barr:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

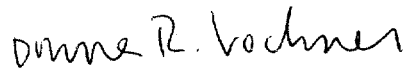
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.


This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

Page 2 – Mr. Bryan Barr

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



 Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 - Statement of Indications for Use**Indications for Use**510(k) Number (if known): 994022Device Name: Parallax Cranioset

Indications for Use:

Parallax Cranioset is a resinous material for repair of cranial defects.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Dan R. Vochnes
(Division Sign-Off)

Division of General Restorative Devices

510(k) Number 994022Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The Counter Use _____
(Optional Format 1-2-96)